UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/463,209	05/12/2000	KORNELIA BERGHOF	2727-99J	6039

7590 01/22/2002

RONALD R . SANTUCCI
FROMMER LAWRENCE & HAUG LLP
745 FIFTH AVENUE
NEW YORK, NY 10151

EXAMINER	
EINSMANN, JULIET CAROLINE	
ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 01/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/463,209	BERGHOF ET AL.	
	Examiner	Art Unit	
	Juliet C Einsmann	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 03 December 2001 .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 2-14 and 24-51 is/are pending in the application.

4a) Of the above claim(s) 10,29 and 34-51 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 3-9,11-14,24-30,32 and 33 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, species SEQ ID NO: 1, in Paper No. 20 is acknowledged. The traversal is on the ground(s) that there is unity of invention in the pending claims and there is no undue or serious burden in searching and examining all of the claims of groups I and II. Applicant asserts that the cancellation of claims 1, 2, 22 and 23 have rendered the examiners finding that there is a lack of a special technical feature moot because the teachings of Millman do not meet the requirements of the pending claims.

This is not found persuasive because, as a first point, the determination of unity of invention occurs with regard to the claims as originally filed. Nonetheless, even if the determination were made in light of the current claim set, there is still a finding of lack of unity. Each of the instant product claims is anticipated by the teachings of Kunsch *et al.* (CA 2194411 A). Therefore, there is a lack of unity since the broadest claim does not provide a special technical feature over the prior art (see 102 rejections below). PCT Rule 13.2 states "The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes ***over the prior art*** (emphasis added)." Since the kits of the instant product claims are, the claims do not provide a special technical feature over the prior art.

Applicant further argues that there is no serious burden for examination of the claims, pointing out that under 35 USC 121 if no serious burden exists then the claims must be examined together, and applicant cites sections of MPEP 800 to support this position. However, MPEP 800 is written with regard to applications filed under 35 USC 111. The instant case was filed

under 35 USC 371, and thus the relevant standard for separation of the claims is a unity of invention standard. This standard does not require that a substantial burden exist between the subject matter of the two inventions. However, if such a standard did exist, it would indeed be met in the instant separation of the product claims from the method claims. In this case, the two inventions would be separately classified. The separate classification of groups I and II is *prima facie* evidence that the examination of these inventions would place an undue burden on the examiner. Furthermore, the searches required to examine the instantly claimed methods and the instantly claimed probes would be different, requiring a search of different classes, different electronic databases and the use of different key words in such a search. Thus, even if a substantial burden were a requirement under the unity of invention rules, the separation of the instant claims is proper.

The requirement is still deemed proper and is therefore made FINAL.

With regard to the election of species, applicant traversed this requirement, again citing sections of MPEP 800 to support their argument. However, as noted above, this is not the proper section of the MPEP to consider in this application which was filed under 35 USC 371. To the contrary, the standard is again one of unity of invention. Upon reconsideration, however, the examiner has decided to rejoin SEQ ID NO: 2, SEQ ID NO: 3, and SEQ ID NO: 4 with SEQ ID NO: 1, because SEQ ID NO: 2-4 are merely subfragments of SEQ ID NO: 1 and are specific embodiments of many of the instant claims. Therefore, claims which specifically recite SEQ ID NO: 1-4 are considered herein. SEQ ID NO: 5 is not a subsequence of SEQ ID NO: 1, and therefore remains withdrawn from prosecution as non-elected subject matter.

Claims 3-9, 11-14, 24-30, and 32-33 are examined herein. Claims 10 and 29 are withdrawn as being drawn to non-elected SEQ ID NO: 5. Claims 34-51 are withdrawn as being drawn to non-elected method claims. Claims 1, 2, and 15-23 were cancelled by amendment in paper number 20.

2. The references cited on the PCT search report have been considered. If applicant desires for these to be printed on the front page of a patent in the event of an allowance, a 1449 in compliance with all appropriate rules should be filed.

Sequence Rules

3. The CRF filed 7/13/01 has been entered into the STIC database. The global misspelling of "unknown" was corrected throughout the CRF.

4. The sequence listing is redundant. The sequences listed as SEQ ID NO: 1, SEQ ID NO: 13 and SEQ ID NO: 19 are identical to one another. Furthermore, the sequences listed as SEQ ID NO: 14 and SEQ ID NO: 15 are also identical to one another. Such an inclusion is confusing. Correction is required.

Claim Objections

5. Claims 7, 8, 28, and 29 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. An independent claim should contain all of the limitations of the claim from which it depends. In this case the claim specifically is attempting to exclude some of the limitations of the independent claim, and thus the claims are improperly independent.

Specification

6. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

7. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

8. The amendment filed under article 34, 15 October 1999 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. Furthermore, amendments filed under Article 34 "must not go beyond the disclosure of the international application as filed (MPEP 1871)." The added material which is not supported by the original disclosure is as follows: Figures 1-10 constitute new matter because they each recite sequence that are not supported by the specification as originally filed. In this application filed under 35 USC 371, the specification as originally filed is considered to be the specification filed as the international application. The original specification does not discuss any sequences other than those disclosed herein as SEQ ID NO: 1-5. Therefore, the amendment filed 7/13/01 which includes SEQ ID NO: 6-12 and 14-18 also introduces new matter to the disclosure. The sequences identified as SEQ ID NO: 13 and 19 are not new matter because they are identical to SEQ ID NO: 1.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

Second Paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 3-9, 11-14, 24-30, and 32-33 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite over the use of the transitional phrasing "characterized by" because it is not clear if this language is intended to be open or closed claim language. For the purposes of this action, "characterized by" has been interpreted as open claim language identical to "comprising." To overcome this rejection applicant should amend the claim using proper transitional language.

Claims 4 and 25 are generally unclear. First, they are indefinite over the recitation "makes it possible by means of a nucleic acid amplification and/or nucleic acid hybridisation methods" and "the distinction is possible by virtue of a differing nucleic acid sequence" because it is unclear how a nucleic acid makes a method possible. The probe itself is a nucleic acid which may be useful as a tool in a method, but it is not clear how it makes the method possible (in this case the to distinguish between bacteria). Second, the phrase "the distinction" in lines 10-11 of claim 4 and line 5 of claim 25 lacks proper antecedent basis in the claims because the claim does not previously mention a distinction. Third, line 12 of claim 4 and line 6 of claim 25 recites "at at" which is unclear language. Fourth, the claims are indefinite over the recitation of "at least one base position in the region of SEQ ID NO: 1" because it is not clear what nucleic acids are considered to be "in the region." It is not clear if this language encompasses only nucleotides within SEQ ID NO: 1 or flanking nucleotides. Overall, claims 4 and 25 do not clearly set out a structure for the at least one probe required in the kit. It is not clear if the probe

must comprise SEQ ID NO: 1, comprise a sequence different from SEQ ID NO: 1, or comprise a portion of SEQ ID NO: 1, or if any of these is sufficient to meet the limitations of claims 4 or 25. This is especially unclear for claim 25 because it excludes a molecule that "has" a sequence according to figures 1 to 10. The claim language "has" is open language, identical in meaning to "comprising." Thus, this exclusion specifically excludes any nucleic acid molecule that comprises one of the sequences listed in figures 1 to 10. One of these sequences, SEQ ID NO: 19 is identical to instant SEQ ID NO: 1. Therefore, this exclusionary proviso excludes any sequence which comprises SEQ ID NO: 1.

Claims 5 and 26 are indefinite over the recitation of "makes it possible..." and "the distinction is possible" for the reasons discussed in the analysis of claims 4 and 25. It is not clear what "under reaction conditions known per se to distinguish" means. It is not clear who the conditions are known to or what the conditions are. Furthermore, it is not clear how reaction conditions themselves distinguish between bacteria. The phrase "the distinction" lacks proper antecedent basis in the claim because the claim does not previously mention a distinction. Overall, claims 5 and 26 do not clearly set out a structure for the at least one probe required in the kit. It is not clear if the probe must comprise the recited portions of SEQ ID NO: 1, comprise a sequence different from the recited portions SEQ ID NO: 1, or comprise fragments of the portions of SEQ ID NO: 1 recited in the claim, or if any of these is sufficient to meet the limitations of claim 5. With regard to the exclusion in claim 26, this is especially unclear. because it excludes a molecule that "has" a sequence according to figures 1 to 10. The claim language "has" is open language, identical in meaning to "comprising." Thus, this exclusion specifically excludes any nucleic acid molecule that comprises one of the sequences listed in

figures 1 to 10. One of these sequences, SEQ ID NO: 19 is identical to instant SEQ ID NO: 1. Therefore, this exclusionary proviso excludes any sequence which comprises SEQ ID NO: 1. It is not clear if applicant intending to claim that the sequences which meet the limitations of claim 26 but are shorter than all of the sequences recited in the figures (and therefore do not "comprise" one of the sequences recited in the figures) or if there is some other meaning in this limitation.

Claims 7 and 8 are indefinite because they recite a nucleic acid molecule "having a sequence that is shorter than a nucleic acid molecule according to claim 6," yet claim six does not recite a length limited nucleic acid. Claim 6 recites a nucleic acid molecule that "has" SEQ ID NO: 1, which is open claim language encompassing sequences which comprise SEQ ID NO: 1, thus the sequences encompassed by claim 6 may be identical to SEQ ID NO: 1 or longer than SEQ ID NO: 1. Absent a clear length limitation in claim 6, claims 7 and 8 are indefinite.

Claim 7 is further indefinite over the recitation "a sequence of the region" because it is not clear what it means to be "of the region" recited. It is not clear if that means the nucleic acid must be a fragment of the region recited or from some part of the genome that is near the recited region but not within the recited region. Clarification is required.

Claims 9 and 11-14 are indefinite because they depend from cancelled claim 1. Claims 30, 32, and 33 are indefinite because they depend from cancelled claim 22. Therefore it is unclear what these claims encompass. An attempt to examine the text of these claims as written has been made, but in light of the lack of clarity with regard to dependency these claims are impossible to fully consider.

Claim 9 is further indefinite over the recitation "but in respect of its sequence in at least 10 successive nucleotides of its nucleotide chain" because this language is cumbersome and unclear. Furthermore, the preamble of claim 9 recites a dependency from claim 1, yet the sections (i)-(iv) appear to recite dependency any one of the preceding claims. Thus, it is not clear from which claim (or claims) claim 9 depends.

Claims 12, 13 and 14 are is further indefinite over the recitation of "where appropriate" because it is not clear where the modifications discussed would be appropriate. Furthermore, it is not clear if the language following "where appropriate" is a limitation of the claim. Claims 12 and 14 further recite the language "modified in a manner known per se for analytical detection methods." This language is unclear because it is not clear what modifications are encompassed by this limitation or to whom they are known. In these claims the phrase "especially" renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. This is true for each instance where the phrase "especially" is used.

Claim 13 is further indefinite over the recitation of "by analogous components known per se for probes and/or primers" because it is not clear what components are encompassed within this limitation or to whom they were known.

Claim 14 is indefinite over the recitation of "in that it comprises" because it is not clear what the antecedent to "it" is. It is not clear if "it" is referring to the nucleic acid molecule or the label.

Claims 28 and 29 are indefinite because they recite a nucleic acid molecule "having a sequence that is shorter than a nucleic acid molecule according to claim 27," yet claim 27 does not recite a length limited nucleic acid. Claim 6 recites a nucleic acid molecule that "has" SEQ

ID NO: 1, which is open claim language encompassing sequences which comprise SEQ ID NO: 1, thus the sequences encompassed by claim 6 may be identical to SEQ ID NO: 1 or longer than SEQ ID NO: 1. Absent a clear length limitation in claim 27, claims 28 and 29 are indefinite.

Claim 28 is further indefinite over the recitation "a sequence of the region" because it is not clear what it means to be "of the region" recited. It is not clear if that means the nucleic acid must be a fragment of the region recited or from some part of the genome that is near the recited region but not within the recited region. Clarification is required.

Regarding claim 32, the phrase "preferably" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

First Paragraph

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. MPEP 2163.06 notes "If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen , 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)."

In the instantly rejected claims, the limitation of "excluding a nucleic acid molecule that has a sequence according to Figures 1 to 10" in claims 24, 25, and 25 appears to represent new

matter. No specific basis for this limitation was identified in applicant's paper, nor did a review of the specification by the examiner find any basis for the limitation. Specifically, the exclusion proviso in which "a nucleic acid molecules that has a sequence according to Figures 1 to 10" are distinguished is not found in the specification. As noted by MPEP 2173.05(i),

> "Any negative limitation or exclusionary proviso must have basis in the original disclosure. See Ex parte Grasselli , 231 USPQ 393 (Bd. App. 1983) aff'd mem., 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement."

Since no basis has been identified, the claims are rejected as incorporating new matter. It is noted that this amendment was originally made in an article 34 amendment to the international application. As discussed above, the original international application is considered to be the specification as originally filed, so any subsequent amendments made must have basis therein.

12. Claims 3-9, 11-14, 24-30, and 32-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current claims are drawn to a nucleic acids as well as kits for the analytical detection of bacteria of the genus Staphylococcus which comprise nucleic acid probes. The specification provides SEQ ID NO: 1, and identifies specific regions of SEQ ID NO: 1 have high variability compared to other Staphylococcal species, and are therefore useful for determining species specific probes (p. 15). SEQ ID NO: 1 is from the species S. aureus. The specification does not provide the sequence corresponding to SEQ ID NO: 1 for any other species. Furthermore, in the

examples, the specification clearly demonstrates that the nucleic acids of the instant invention are only able to detect S. aureus.

The claims encompass nucleic acid sequences for the detection of any bacteria within the genus Staphylococcus. Furthermore, the claims specifically require in some instances that the claimed sequences be "different from" SEQ ID NO: 1. However, the specification provides no guidance as to what differences in SEQ ID NO: 1 would be useful for the determination of the presence or absence of species other than S. aureus. Thus, applicant has express possession of only one species (a probe consisting of SEQ ID NO: 1) in a genus which comprises hundreds of millions of different possibilities. It is noted that from within this single exemplified sequence three additional probes are given, named as SEQ ID NO: 2-4. These are also considered to be properly described.

Furthermore, claims 24-26 appear to exclude sequence having SEQ ID NO: 1, and therefore are claiming only sequences which do not have SEQ ID NO: 1, a genus for which there is no description. The claim language "has" is open language, identical in meaning to "comprising." Claims 24-26 exclude any nucleic acid which "has" a sequence as set forth in figures 1-10. Thus, this exclusion specifically excludes any nucleic acid molecule that comprises one of the sequences listed in figures 1 to 10. One of these sequences, SEQ ID NO: 19 is identical to instant SEQ ID NO: 1. Therefore, this exclusionary proviso excludes any sequence which comprises SEQ ID NO: 1.

With regard to the written description, all of these claims encompass nucleic acid sequences different from those disclosed in the specific SEQ ID No:s which, include modifications by permitted by the % identity language as well as for "base pair differences" for

which no written description is provided in the specification. Furthermore, it is noted that the kit claims all recite kits for the detection of bacteria in the genus Staphylococcus when only nucleic acids for the detection of one such bacteria, S. aureus, is provided.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the nucleic acids of the disclosed SEQ ID Nos are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids modified by addition, insertion, deletion, substitution or inversion with the disclosed SEQ ID No: 1 but possessing one such that a different nucleic acid sequence is retains S. aureus detecting function or such that the nucleic acid has the ability to detect other species of Staphylococcus.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 3-9 and 24-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Kunsch *et al.* (CA 2194411).

This document is a "laid open" Canadian patent application. When the application is "laid open" all parts of the application as filed become available to the public. In the instant case, the Canadian patent office did not publish the sequence listing for CA 2194411 A1. However, the full sequence listing was available to the public on the day the application was laid open. Accompanying this action are copies of the specifically cited sequences provided from EP 0786519 A. It is assumed that this sequence listing is identical to that in the CA 2194411 A1 application.

Kunsch *et al.* teach kits comprising more than one nucleic acid probes, wherein at least one of the nucleic acid molecules hybridizes selectively to the RNA or DNA of S. aureus. Kunsch *et al.* provide, in 5,191 sequences, polynucleotides of the genome of S. aureus (p. 7). Kunsch *et al.* teach fragments that can be used to diagnose S. aureus (DF's) (p. 8, line 8) and kits which comprise these fragments (p. 42, line 24-p. 44, line 12). Many of the sequences taught by Kunsch *et al.* meet the limitations of the instant claims.

For example, SEQ ID NO: 3803 taught by Kunsch *et al.* comprises SEQ ID NO: 1. Instant SEQ ID NO: 1 is the complement of 26-196 of Kunsch *et al.*'s SEQ ID NO: 3803.

As another example, SEQ ID NO: 4725 taught by Kunsch *et al.* comprises part of nucleotides 54-83 of instant SEQ ID NO: 1, but is shorter than SEQ ID NO: 1. Nucleotides 106-134 of SEQ ID NO: 4725 are identical to nucleotides 54-82 of SEQ ID NO: 1. Therefore, SEQ ID NO: 4725 also comprises SEQ ID NO: 2.

As a third example, SEQ ID NO: 5094 taught by Kunsch *et al.* comprises nucleotides 100-166 of instant SEQ ID NO: 1, but is shorter than instant SEQ ID NO: 1. Kunsch *et al.*'s SEQ ID NO: 5094 consists of 51 nucleic acids which are identical to nucleotides 83-135 of instant SEQ ID NO: 1. Therefore, SEQ ID NO: 5094 also comprises SEQ ID NO: 4 which are found at positions 102-121 of SEQ ID NO: 1.

These sequences would hybridize selectively to S. aureus, and each contain at least ten nucleotides from position 54 to 83 of SEQ ID NO: 1, or position 100 to 166 of SEQ ID NO: 1, or sequence complementary to these regions. These sequences could be used to distinguish between S. aureus and other sequences via a hybridization assay. At least one of these sequences "has" (i.e. comprises) instant SEQ ID NO: 1.

Kunsch *et al.* provide many additional nucleic acids whose sequences meet the limitations of at least one, if not all, of the rejected claims. Specific identification of these nucleic acids would have been duplicative of the three mentioned examples.
At least one of the probes taught by Kunsch *et al.* contains at least 10 successive nucleotides from the region from nucleotides 54 to 83 of SEQ ID NO: 1.

Conclusion

15. Claims 9, 11-13, 30, and 32-33 have not been rejected under the art because it is impossible to determine what these claims are intended to comprise in light of their dependence from cancelled claims.

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Green *et al.* (GenBank L36472, 11 November 1994) provide a nucleic acid sequence

which comprises the 5s-23s spacer region of Staphylococcus aureus. The sequence taught by Green *et al.* comprises instant SEQ ID NO: 1.

17. No claims are allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Juliet C. Einsmann
Examiner
Art Unit 1655

January 17, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600